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Sterling Medivations, Inc.
25285 La Loma Drive
Los Altos Hills, CA 94022
650-949-0470 (voice)
650-949-0342 (fax)

K012330

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510(k) SUMMARY

Date Submitted: July 20, 2001

Submitter: Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391 Company Phone 952-473-7971, Company fax 952-473-4758

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-949-0470, Applicant Fax 650-949-0342

Trade Name of Device: Simplicity™ Euro QD Euro Infusion Set for use by people with diabetes to infuse insulin subcutaneously from a pump or syringe.

Common Name of Device: Intravascular administration set.

Classification Name: Percutaneous intravascular catheter.

Predicate Device: The predicate device for Sterling's Simplicity™ Euro QD Infusion set is the MiniMed® Sof-Set Ultimate MMT 315 and MMT-316 Infusion Set, K974163.

Description of the New Device: Sterling Medivations, Inc.'s ("SMI") Simplicity ™ Euro QD Infusion Set is designed for use by people with diabetes to infuse insulin subcutaneously from a pump or syringe.

The Simplicity ™ Euro QD Infusion Set proposed for commercial distribution is similar in all significant respects to the existing the MiniMed® Sof-Set Ultimate MMT 315 and MMT-316 Infusion Set, K974163 and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from AISI 304 stainless steel, (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a female Luer pump connector.

The Simplicity Euro QD Infusion Set is an infusion administration set, connecting to a pump or syringe and inserted in the subcutaneous tissue of a patient. The Sterling Medivations Simplicity Euro QD Infusion Set may be used with any infusion device that delivers continuous or intermittent flow.

The administration set attaches to the pump or syringe by means of a female Luer connector, and subcutaneously in the patient through an indwelling catheter made of AISI 304 stainless steel. The connecting tubing is made from a polyethylene tube.

The 27 gauge-indwelling catheter is introduced into the subcutaneous tissue. A connector needle is attached to the hub fixed to the indwelling catheter. This connector needle pierces a septum forming a seal that permits the infusion of medication without leakage. The connector needle is connected to the connecting tubing and a connector housing. The connector tubing proximal end is attached to a female Luer connector for attachment to the medicine reservoir. The connecting tube is solvent bonded to the connector housing and to the Luer connector. The quick disconnect allows the patient to temporally disconnect the pump reservoir from the indwelling catheter to better facilitate bathing and reservoir changes.

Intended Use of the New Device: The intended use of the Simplicity Euro QD Infusion Set is to provide a means to infuse or inject insulin subcutaneously when the device is attached to a pump or syringe

Comparisons of the Technological Features of the New Device and Predicate Device:

The Simplicity Euro QD Infusion Set proposed for commercial distribution is similar in all significant respects to the existing MiniMed® Sof-Set ULTIMATE MMT 315 and MMT-316 Infusion Set 510(k) K974163.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the MiniMed® Sof-Set ULTIMATE MMT 315 and MMT-316 Infusion Set FDA 510(k) K974163.

The differences that exist between the new and predicate device are as follows:

1) The Simplicity Euro QD Infusion Set has a connecting tube of Polyethylene and the predicate device has a connecting tube of co-extruded connecting tube Polyethylene id and PVC OD.

2) The Simplicity Euro QD Infusion Set has a quick disconnect that is built into the infusion housing. The predicate device has a quick disconnect fitting spliced into the connecting tube. The ability for the Sterling Medivations Simplicity Euro QD Infusion Set to connect and disconnect at the infusion site makes for an easier to use and more comfortable device than the predicate device.

3) The Simplicity Euro QD Infusion Set has an AISI 304 stainless steel infusion needle and the predicate device has a soft cannula made from Fluorinated Ethylene Propylene (FEP). The AISI 304 stainless steel infusion needle is substantially equivalent to the Sterling Medivations Simplicity with Wings Infusion Set FDA 510(k) K003283

Performance Data Supporting Substantial Equivalence: To provide substantial equivalence the Simplicity Euro QD Infusion Set meets the catheter requirements of:

CDRH 21 C.F.R. section 880.54400 Intravascular administration set,
ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements), and
ISO 10555 Sterile, single use intravascular catheters (Part 5: peripheral catheters).,
ISO 9626 Stainless steel needle tubing for the manufacture of medical devices,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2:1994 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization.
ISO 594-1: 1986 Conical fittings with a 6%)Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements,
ISO 594-2: 1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings,
ISO 11607: 1997 Packaging for terminally sterilized medical devices,
ISO 8537: 1991 Sterile single use syringes, with or without needle for insulin,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2: 1994 Sterilization of health care products – Biological indicators – Part 2:Biological indicators for ethylene oxide sterilization.

FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices. ODE Blue Book Memorandum #K90-1.

The design process adhered to is the Center of Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CGR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. Joel S. Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
25285 La Loma Drive
Los Altos Hills, California 94022-4583

Re: K012330
Trade/Device Name: Simplicity Euro QD Infusion Set
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: July 20, 2001
Received: July 23, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Simplicity Euro QD Infusion Set

Indications For Use:

The intended use of the Simplicity Euro QD Infusion Set is to provide a means to infuse insulin subcutaneously from a pump or syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ___
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012330